K031849
p1/3

SEP - 9 2003

510(k) Summary of Safety and Effectiveness

Date: June 13, 2003

Submitter: Patient Monitoring Division
Datascope Corp.

Contact Person: Susan E. Mandy
Director, Clinical & Regulatory Affairs
Patient Monitoring Division
Datascope Corp.
Telephone: (201)995-8025
Fax: (201)995-8605

Device trade name: Spectrum Monitor

Common/usual name: Multi-parameter patient monitor (with Arrhythmia Detection or Alarms)

Classification names:

21 CFR 868.1400 -Analyzer, Gas,Carbon-Dioxide, Gaseous-Phase
21 CFR 870.1025- Arrhythmia detector and alarm
21 CFR 870.1110- Blood Pressure computer
21 CFR 870.1130- Non-invasive blood pressure measurement system
21 CFR 870.1425- Programmable diagnostic computer
21 CFR 870.1435 - Single-function, pre-programmed diagnostic computer
21 CFR 870.2300-Cardiac Monitor (Incl. Cardiotachometer and rate alarm)
21 CFR 870.2700- Oximeter
21 CFR 880.2910-Monitor, Temperature (with probe)

Predicate Devices: K020550 Passport 2® Vital Signs Monitor with View 12™ ECG Analysis Module
K030431 GE Medical Systems Dash 3000/4000 Patient Monitor

Device Description: The Spectrum Monitor is an enhanced version of the Datascope Corp. Passport 2® Vital Signs Monitor with View 12™ ECG Analysis Module, previously cleared by FDA under K020550. There have been no significant changes to the Passport 2® Vital Signs Monitor with View 12™ ECG Analysis Module since its clearance. Datascope Corp. has modified the Passport 2® Vital Signs Monitor with View 12™ ECG Analysis Module by including the following parameters: Cardiac Output, Drug Calculations, Hemodynamic Calculations, a second Temperature, and two additional Invasive Blood Pressure Channels.

The Spectrum monitor is a device that is used to monitor, display, trend and print a patient's physiological parameters. The device has a 12.1 inch color display and has a standard configuration of a 3 or 5 lead ECG, Masimo SET SpO_2, Non-Invasive Blood Pressure (NIBP), Respiration, Continuous Temperature and IV Drug Calculations. Optional software includes ST and Arrhythmia Analysis. Optional hardware features include View12 ECG Analysis Module (which includes ST

Arrhythmia and 12 Lead interpretation), up to 4 Invasive Blood Pressure Channels, Microstream CO_2, Anesthetic Gases, Nellcor Oximart SpO_2, second temperature source, dual trace recorder, and Cardiac Output. A comprehensive calculation package including Hemodynamic Calculations is available if the Spectrum is equipped with an External Parameter Module.

Digital displays are provided for Heart Rate, NIBP, SpO_2, Respiration Rate, and Temperature. Optional digital displays are provided for up to four Invasive Blood Pressure, Anesthetic Agents, O_2, and N_20, ST and CO_2. The optional internal recorder provides hard copies of all digital data and waveforms, as well as trend information.

Intended Use: The Spectrum monitor is intended for intra- hospital use under the direct supervision of a licensed healthcare practitioner. The indications for use for the Spectrum device include the monitoring of the following human physiological parameters:

ECG waveform derived from 3, 5 or 12 lead measurements
Heart Rate derived from selected sources (ECG, SpO_2, IBP, NIBP)
Pulse Oximetry (SpO_2)
ST Segment Analysis derived from 3, 5 or 12 ECG lead measurements
Arrhythmia Detection derived from 3, 5 of 12 ECG lead measurements
Interpretation of Resting 12 lead ECG
Non Invasive Blood Pressure (NIBP)
Invasive Blood Pressure (IBP) - up to four (4) channels
Cardiac Output
Respiration Rate/ waveform derived from ECG or CO_2
CO2, inspired and end tidal microstream/ waveform
Temperature - up to two channels
Hemodynamic Calculations
IV Drug Calculations

The target populations are adult, pediatric and neonate with the exception of the:
Arrhythmia detection, ST Segment Analysis, Cardiac Output, Hemodynamic Calculations, and Pulmonary Artery Wedge Pressure measurements, for which the target populations are adult and pediatric only, and
Interpretation of Resting 12 Lead ECG and IV Drug Calculations, for which the target population is adult only.

The Spectrum monitor has the capability of interfacing with Datascope's Intra Aortic Balloon Pumps, Central Stations and Gas Module products .

Technology: The Spectrum Monitor is substantially equivalent to the Passport 2® Vital Signs Monitor with View 12™ ECG Analysis Module (K020550) and the GE Medical Systems Dash 3000/4000 Patient Monitor (K030431).

Test Summary: The Spectrum Monitor complies with the voluntary standards identified in section six of this submission. Datascope's product development process required that the following activities be completed during the development of the Spectrum monitor:

Requirements specification review
Hardware and software testing
Code design and code reviews
Environmental/EMC testing
Safety testing
Performance testing
Hardware and Software validation

Conclusion: The results of all testing demonstrate that the Spectrum Monitor is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2003

Datascope Corporation
c/o Ms. Susan E. Mandy
Director, Clinical and Regulatory Affairs
Patient Monitoring Division
800 MacArthur Blvd.
Mahwah, NJ 07430-0619

Re: K031849
Trade Name: Spectrum Patient Monitor
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm.
Regulatory Class: Class III (three)
Product Code: MHX
Dated: June 13, 2003
Received: June 16, 2003

Dear Ms. Mandy:

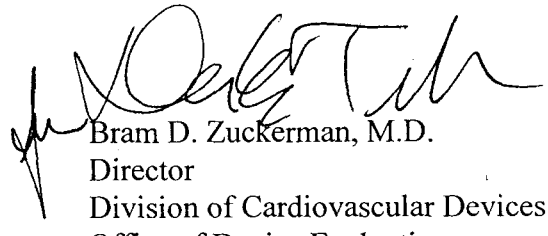
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031849

Device Name: Spectrum Patient Monitor

Indications For Use:

The Spectrum monitor is intended for intra hospital use under the direct supervision of a licensed healthcare practitioner. The indications for use for the Spectrum device include the monitoring of the following human physiological parameters:

- ECG waveform derived from 3, 5 or 12 lead measurements
- Heart Rate derived from selected sources (ECG, SpO_2, IBP, NIBP)
- Pulse Oximetry (SpO_2)
- ST Segment Analysis derived from 3, 5 or 12 ECG lead measurements
- Arrhythmia Detection derived from 3, 5 of 12 ECG lead measurements
- Interpretation of Resting 12 lead ECG
- Non Invasive Blood Pressure (NIBP)
- Invasive Blood Pressure (IBP) - up to four (4) channels
- Cardiac Output
- Respiration Rate/ waveform derived from ECG or CO_2
- CO2, inspired and end tidal microstream/ waveform
- Temperature - up to two (2) channels
- Hemodynamic Calculations
- IV Drug Calculations

The target populations are adult, pediatric and neonate with the exception of the:

- Arrhythmia detection, ST Segment Analysis, Cardiac Output, Hemodynamic Calculations, for which the target populations are adult and pediatric only, and
- Interpretation of Resting 12 Lead ECG and IV Drug Calculations for which the target population is adult only.

The Spectrum monitor has the capability of interfacing with Datascope's Intra Aortic Balloon Pumps, Central Stations and Gas Module products.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031849

Prescription Use Only

(Optional Format 3-10-98)